

### **REMARKS**

New Claims 71 and 72 have been submitted.

Claim 71 is drawn to a method of treating metastatic cancer in a mammal, the method comprising introducing into the mammal a viral vector expressing Fas ligand. Support for this claim can be found in the specification, for example, on page 54, lines 23-26, and on page 55, lines 24-28.

Claim 72 specifies the pharmaceutically acceptable carrier comprising the recombinant viral vector is introduced at a site adjacent to said metastatic cancer cells. Support for this claim can be found in the specification, for example, on page 55, lines 11-14.

#### **I. Rejections under 35 U.S.C. § 102**

The Examiner has rejected Claims 64, 66 and 69 as being anticipated by Arai et al. (PNAS 94(25):13862-13867, 1997). Specifically, the Examiner characterizes Arai et al. as teaching that Fas antigen is a cell-surface receptor that transduces apoptotic signals into cells in response to Fas ligand (Fas L). The Examiner further characterizes Arai et al. as teaching that gene transfer of Fas ligand induces tumor regression in vivo, as does injection of tumors with ADV-FasL. Thus the Examiner concludes that, because the instant claims encompass the direct injection of a viral vector encoding Fas L into a metastatic cancer cell, and because a metastatic cancer cell is indistinguishable from any other cancer cell, the present claims are anticipated by the teaching of Arai et al.

As acknowledged by the Examiner, in order to anticipate under 35 U.S.C. §102, a prior art reference must disclose each and every element of a claim within the four corners of a single document. The disclosure of Arai et al. does not pass this test. The instant claims are drawn to a method of inducing apoptosis in cancer cells in a mammal, by administering to said mammal a viral vector expressing Fas ligand. Importantly, all of the claims recite that the cells being affected or treated are metastatic cancer cells. Arai et al. does not teach the treatment of metastatic cells. In fact, the term metastatic (metastases, etc.) does not even appear in the disclosure of Arai et al. Thus Arai et al. does not disclose every element of the presently claimed invention. In this regard, the Examiner states that a metastatic cancer is indistinguishable from

any other cancer. Consequently, the Examiner does not give any weight to the term "metastatic". However, such dismissal of this term is impermissible for the following reasons.

To begin with, limitation of the presently claimed methods to metastatic cells is a key element of the claimed invention. However, the Examiner dismisses this key element without providing any evidence showing that a metastatic cancer is indistinguishable from any other cancer. Moreover, the Examiner is incorrect in stating that metastatic cancer is indistinguishable from any other cancer. It is well known in the art that metastatic cells have characteristics that differentiate them from non-metastatic cells (e.g., their cells of origin). In support of this statement, Applicants submit Exhibit A, which teaches that metastatic cells develop characteristics such as motility due to down-regulation of cell-cell and cell-matrix adhesion molecules, the ability to move through the basement membrane, and the ability to extravasate out of blood or lymphatic vessels. Such characteristics are not observed in non-metastatic cells and thus, metastatic cells are clearly distinguishable from other cancers. In view of this, Applicants contend the term "metastatic" in the claims is a significant element that must be given weight. Moreover, since Arai et al. does not teach, or even mention, metastatic cells, Arai et al. does not disclose every element of the presently claimed invention. Therefore, Arai et al. does not anticipate the present invention.

### **CONCLUSION**

Based on the foregoing, Applicants believe that all pending claims are in condition for allowance and such disposition is respectfully requested. In the event that a telephone conversation would further prosecution and/or expedite allowance, the Examiner is invited to contact the undersigned.

Respectfully submitted.

SHERIDAN ROSS P.C.

Date: 2/11/10

By: Richard J. Stern  
Richard J. Stern  
Registration No. 50,668  
1560 Broadway, Suite 1200  
Denver, Colorado 80202-5141  
(303) 863-2975